



## **Russian Pharmaceutical Market Trends in 2017**

Track & trace system: additional costs or opportunities?

Deloitte CIS Research Centre  
Moscow, 2017



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# Introduction



**Oleg Berezin**  
Partner  
Head of Life Sciences  
& Healthcare Industry  
group in the CIS

Deloitte CIS would like to thank all of the participants of the survey, which was held in August 2017 as part of the research project “Russian Pharmaceutical Market Trends in 2017”, for their time and interest. Your expert opinions allowed us to conduct an integrated analysis of the situation on the Russian pharmaceutical market, as well as to study your views and expectations regarding the prospects for your own company’s development and the market overall.

Our recent survey includes the views of respondents from 58 Russian and foreign generic and original drug manufacturers in Russia and abroad, including pharma distributors.

We are pleased to present the full report. We hope that you will find it useful and informative.

We would be grateful if you would participate in our next survey.

Please feel free to contact us if you have any questions about the report.

Even though the Russian pharmaceutical market has been demonstrating an overall stable growth, particularly in ruble terms, the growth rates over 2013–2016 are down by nearly two times, from 14 percent to 7 percent.

As an area of high social and economic importance, the pharmaceutical industry is under close government scrutiny where decisions by authorities set a development path for the whole industry. The industry is waiting for a new, mandatory medicine labeling and distribution monitoring (track & trace) framework to go live. This framework is designed to protect consumers against counterfeit drugs and provide the business community and the government with a transparent view of product flows.

As one of the most high-tech intensive industries, the pharmaceutical sector is characterized by rapid changes in product offerings. While staying competitive in the industry requires a continuing flow of financial support and rigorous innovation, pharmaceutical investments can generate lucrative returns, with the industry itself having the potential to become one of the powerhouses of the Russian economy.

## Key topics:

- Analysis of the key statistics of the pharmaceutical market and the pharma industry in Russia
- Russian pharma industry: recent developments and future prospects
- Pharmaceutical companies in Russia: recent developments and future prospects
- Pharmaceutical companies in Russia: development strategies
- Cost optimization approaches
- Track & trace system
- Top-14 issues facing pharmaceutical companies in Russia
- Trading policies on the Russian pharmaceutical market
- Expert opinion: priority regulatory areas for improvement
- Regulatory measures aimed at reducing the share of pharmaceutical imports.

Best regards,  
**Oleg Berezin**



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# Key findings

## Market snapshot

In 2016 the pharmaceutical market grew by 6.7 percent in ruble terms while remaining unchanged from 2015 in unit terms.

Market growth forecasts for 2017 (in ruble terms):

- DSM Group: up by 8-9 percent
- RNC Pharma: up by 10 percent
- QuintilesIMS: up by 9.2 percent

Market growth forecasts for 2017 (in unit terms):

- DSM Group: up by 1-2 percent
- QuintilesIMS: up by 4.8 percent;
- IPT Group: up by 4-6 percent.

In 2016 pharmaceutical price inflation was 5 percent.

The share of local medicines grew by 1.2 pp in monetary terms.

The Russian market is ranked 14th in the world in terms of size.

In Russia pharmaceutical output increased by 23.8 percent to RUB 286 billion while medical product output grew by 15 percent to RUB 52.8 billion.

Output forecast for 2017 by the Russian Ministry of Industry and Trade:

- Medicines: up by 8 percents
- Medical products: up by 4 percent

By the end of 2016 medicines produced in Russia accounted for 77 percent of the Essential Drug List.

In 2016 almost 80 percent of imports came from Europe, primarily from France and Germany.

The post-Soviet countries remain the major export markets for Russian medicines, accounting for 86 percent of the total exports.

## Pharmaceutical market perception

View of the current state of:

- Pharma industry—positive perception (a balance of +52 percent)
- Pharmaceutical businesses—positive perception (a balance of +82 percent)

View of the future prospects of:

- Pharma industry—neutral perception (a balance of +7 percent)
- Pharmaceutical businesses—positive perception (a balance of +42 percent)

Change in the share of imports as expected by the Russian market: down by 3 percent in monetary terms and by 4 percent in unit terms.

Demand for regulatory measures aimed at reducing the share of pharmaceutical imports: localization incentives and privileges for foreign companies, as well as subsidies and privileges for Russian companies.

Demand for more efficient regulation

- Medicine pricing (87 percent)
- Public procurement regulation (74 percent)
- Regulation of on-line sales of medicines and telehealth (67 percent)
- State registration of medicines (67 percent)
- Mandatory track & trace framework (67 percent)

## Business development strategy

Medicine labelling is a new regulatory trend that is likely to have an impact on how companies and the industry as a whole will develop.

A focus on new product launches is the top development strategy for pharmaceutical companies in Russia.

New trends in strategic development: focus on R&D activities and deeper localization.

Top challenges: stronger competition and a shift of the focus to gaps in the industry regulation.

Expectations for key indicators:

- Most companies (82 percent) expect an average growth of 13 percent in ruble terms in 2017
- Of those surveyed, 39 percent expect that operating costs will see an average growth of 16 percent while another 26 percent anticipate an average decrease of 11 percent
- Most companies (59 percent) are not planning any headcount adjustments while another 33 percent expect that their headcount will increase on average by 7 percent
- Most companies (63 percent) are planning to increase pay levels by 7 percent on average

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# Russian pharmaceutical market in figures

Current state and future prospects

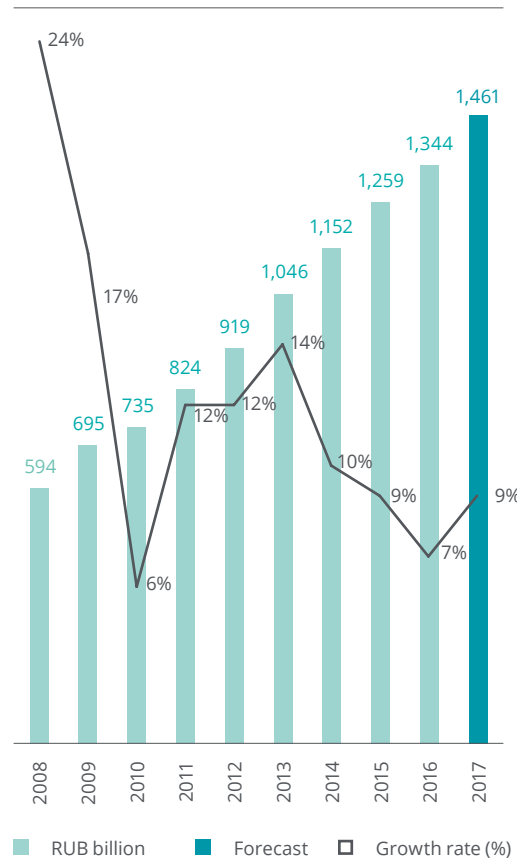


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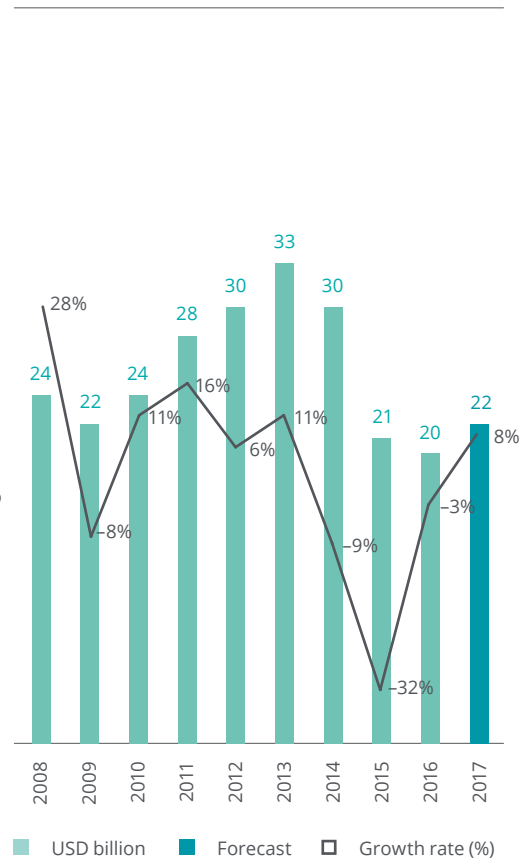


# Analysis of key market indicators: market size

Market size dynamics (RUB billion)



Market size dynamics (USD billion)



**Trend**

The year 2016 saw the Russian pharmaceutical market grow by 6.7 percent in ruble terms while decreasing by 3 percent in US dollar terms due to a weaker weighted average ruble exchange rate.

In 2016 the market saw a positive growth mainly due to the growth in sales (in ruble terms) in 4Q2016.

**Market size forecast for 2017 (in ruble terms):**

**DSM Group: up by 8-9 percent.** According to the forecast, the growth will be primarily driven by sales in the commercial segment.

**RNC Pharma: up by 10 percent.** It is expected that higher consumption, combined with inflation, will be a key driver for growth.

**QuintilesIMS: up by 9.2 percent.**

**Expert view**

“This year is going to be an interesting one. Pilot projects in medicine labelling and risk sharing will have a huge impact. However, a move to implement online sales of medicines is also noteworthy. All of these factors can deliver a significant shift in the market.”

**Pavel Rasshchupkin, Director of Analytics, RNC Pharma in an interview to Pharmatsevticheskiy Vestnik**

**IPT Group:**

“Along with a growth in chronic illnesses, the ageing of the population will result in a higher consumption of medicines.”

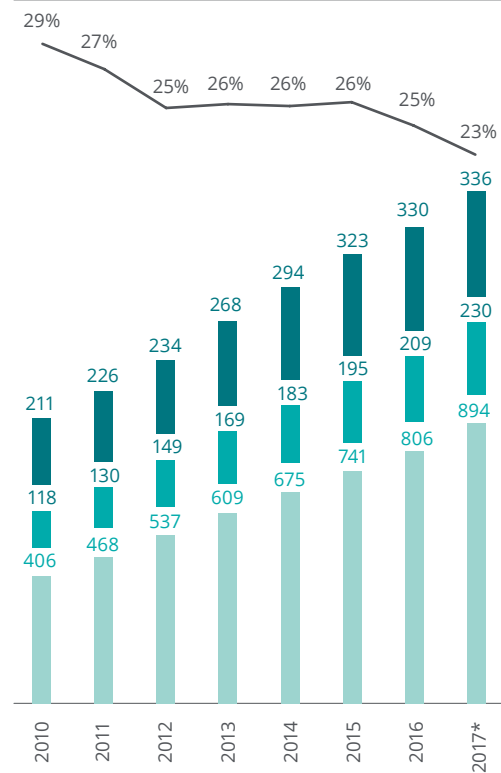
Source: DSM Group, the Central Bank of Russia, the Russian Ministry of Economic Development

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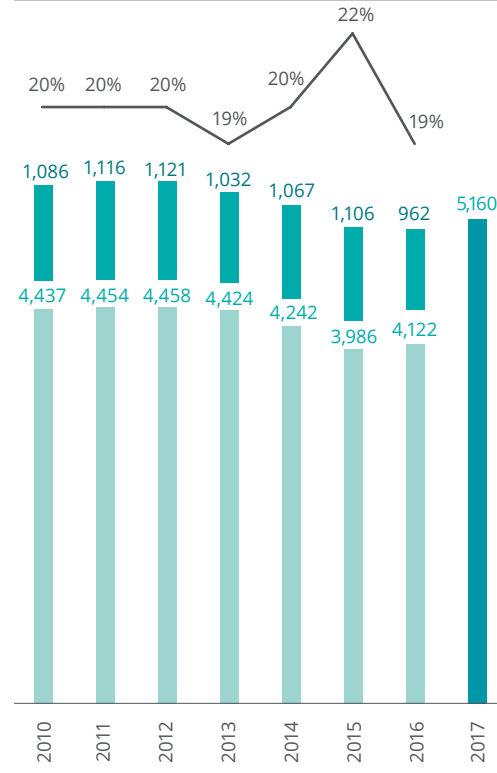


# Analysis of key market indicators: market size by sector

Market dynamics in monetary terms (RUB billion)



Market dynamics in unit terms (in billion packages)



Public sector of Finished pharmaceutical products (FPPs)  
 Commercial sector (parapharmaceuticals)  
 Commercial sector (FPPs)  
 Share of public procurements

Commercial segment (FPPs)  
 Hospital purchases and the State Reimbursement Programmes  
 2017 forecast for the overall market  
 Share of hospital purchases and the State Reimbursement Programmes

\* 2017 forecast  
 Source: DSM Group

**Trend:**

The public sector decreased by 13 percent in unit terms and is continuing to shrink both in monetary and unit terms.

The growth in the market is driven by the commercial segment, which has grown by 8.2 percent in monetary terms and by 3.1 percent in unit terms.

January-April 2017 saw the commercial segment sell 1,460 million packages, which is up by 13.6 percent from the same period in 2016.

**Market size forecast for 2017 (in unit terms):**

- DSM Group: +1-2 percent.
- QuintilesIMS: +4.8 percent.
- IPT Group forecasts: +4-6 percent.

**Expert view:**

“A growth in retail package sales was expected because the market had already reached the bottom.”

**Sergey Shulyak, General Director, DSM Group, 20 March 2017**

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# Analysis of key market indicators: medicine price inflation

Inflation for 2008–2016 (%)



\*According to the Russian Federal Statistics Service, prices for medicines grew by 4.9 percent.

Source: DSM Group, Russian Federal Statistics Service

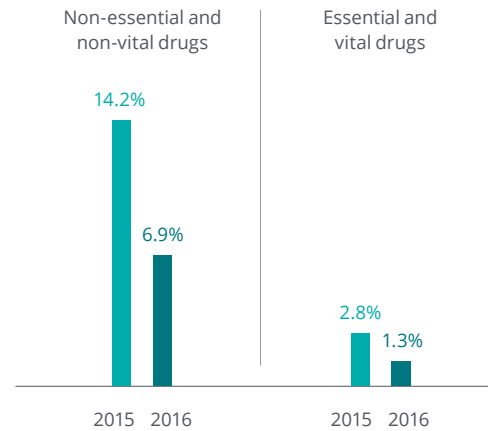
In 2016 inflation in Russia slowed down to 5.4 percent with medicine prices growing by 5 percent, the lowest inflation rate over the last three years.

Due to the regulatory efforts, prices for drugs on the Essential Drug List (EDL) grew at a slower rate (+1.3 percent) compared to other medicines (+6.9 percent).

The market for EDL drugs accounts for about 50 percent of the total market, both in unit and monetary terms.

In 2016 the market for medicines priced below RUB 50 per package saw the most significant grow – 7.1 percent. Prices for expensive medicines valued at RUB 500 or above grew just by 1.9 percent.

In 2016 inflation was the key factor driving the growth in the pharmaceutical market in monetary terms.



Source: DSM Group

**Expert view:**

“Unfortunately, the market for low-priced medicines has seen a downtrend both in ruble and unit terms... The share of medicines priced below RUB 50 is down by almost 2 percent. Here we can actually say that the market is shifting toward more expensive medicines.”

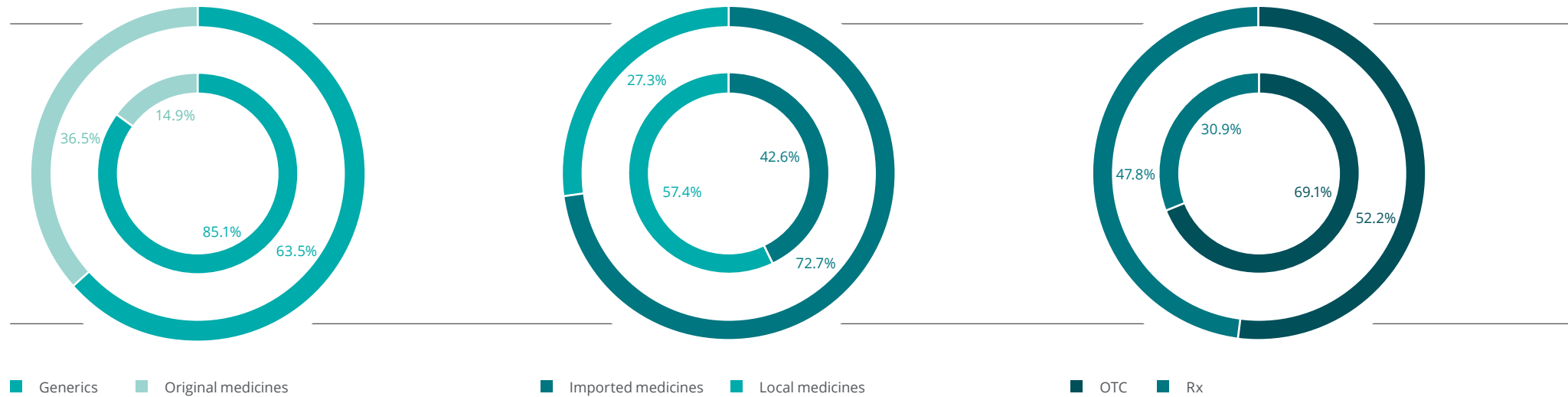
**Sergey Shulyak, General Director, DSM Group, 20 March 2017**



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# Analysis of key market indicators: commercial segment structure by the end of 2016



Inner circle – in unit terms; outer circle – in monetary terms

- The share of original medicines is down by 1.3 pp from 2015, indicating that consumers are shifting to cheaper generics.
- In 2016 the average price per original drug package was RUB 362 while generic medicines had an average price of RUB 111 per package.
- In 2016 the share of local medicines grew by 1.2 pp in monetary terms and by 1 pp in unit terms.
- While sales of local medicines increased by 18 percent, imported medicines only grew by 6 percent in ruble terms, with the average price per package reaching RUB 71 for local medicines and RUB 253 for imported medicines.
- OTC drug sales grew by 11 percent in monetary terms and by 2 percent in unit terms.
- Sales of prescription medicines increased by 7 percent in monetary terms and by 5.5 percent in unit terms.
- The pronounced growth in OTC drug prices is directly due to increased prices for medicines sold below RUB 50, with OTC drugs accounting for 80 percent in this price bracket.

Source: DSM Group

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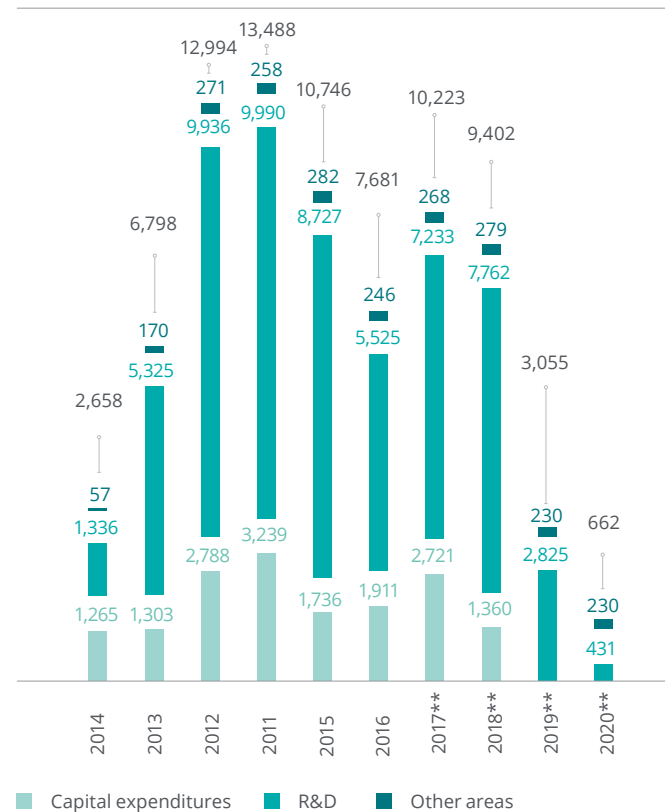


# Regulatory trends in the pharmaceutical industry

The federal program “Pharmaceutical and healthcare industry development for a period until 2020 and thereafter” sets forth the key regulatory tasks:

- Technological upgrade of the pharmaceutical industry;
- Import substitution for drugs on the Essential Drug List;
- Launches of innovative domestic products;
- Stronger export potential of the pharmaceutical industry;
- Availability of human resources necessary for implementing the model of innovation-driven development.

Spending on Pharma 2020\* (RUB million)



\* The federal program “Pharmaceutical and healthcare industry development for a period until 2020 and thereafter”  
 \*\* Expenses provided for in the program’s specifications (“passport”) as amended on 19 June 2016

Source: Russian Ministry of Economic Development

## Expert view

“...one ruble in public investments accounts for almost five rubles in private investments. This enables building new production sites and innovative integrated infrastructure, as well as creating jobs and expanding the tax base.”

Denis Manturov, Russian Minister for Industry and Trade, December 2016



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# Regulatory trends in the pharmaceutical industry

## Trend

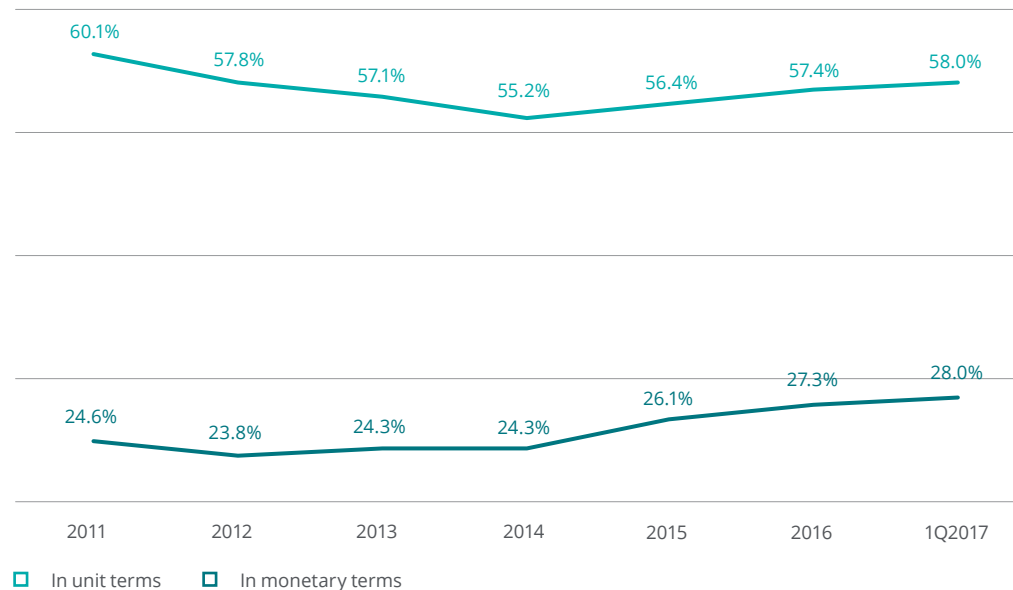
Increased share of local medicines sales have become one of the outputs from the regulatory efforts by the government. The sales have been growing in monetary terms since 2013 and in unit terms since 2015. The more pronounced growth in monetary terms is partially due to an increasing share of more expensive domestic

innovative medicines. This is particularly evident when looking at the segment of preferential provision of medicines, which includes innovative and expensive drugs, with local medicines accounting for 32.3 percent of the segment. In 2016 the average price in this segment was RUB 1,700 per package while the price for the overall market was RUB 265.

For better access to medicines, the programme Pharma 2020 provides that the share of local drugs on the Essential Drug List should increase up to 76 percent by 2016 and up to 90 percent by 2018. This share was about 77 percent by the end of 2016.

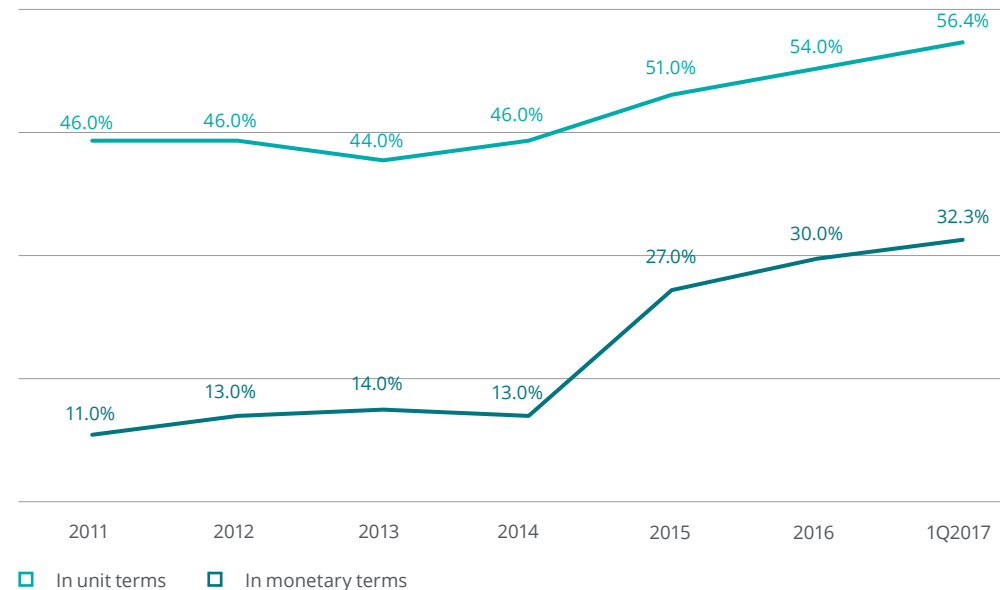
## Share of local medicines over 2011-1Q2017

### As a percentage of total sales



Source: DSM Group

### As a percentage of the segment of preferential provision of medicines



Source: DSM Group

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Medicine price inflation

Segment structure by the end of 2016

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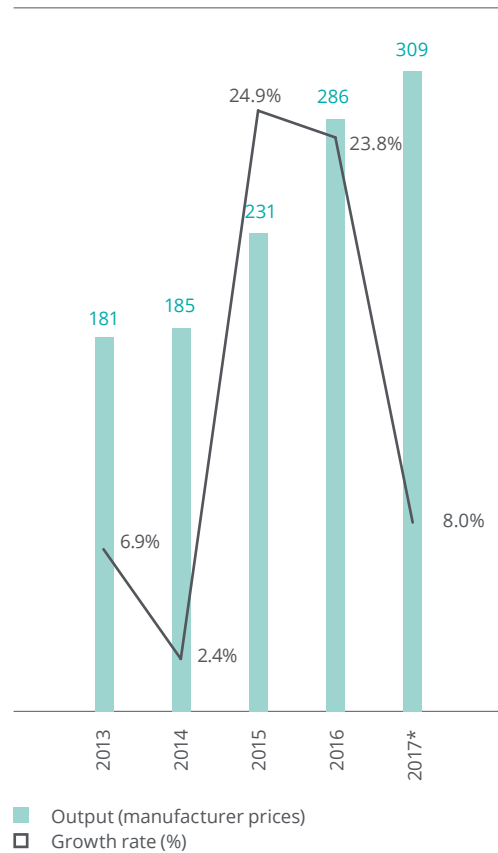
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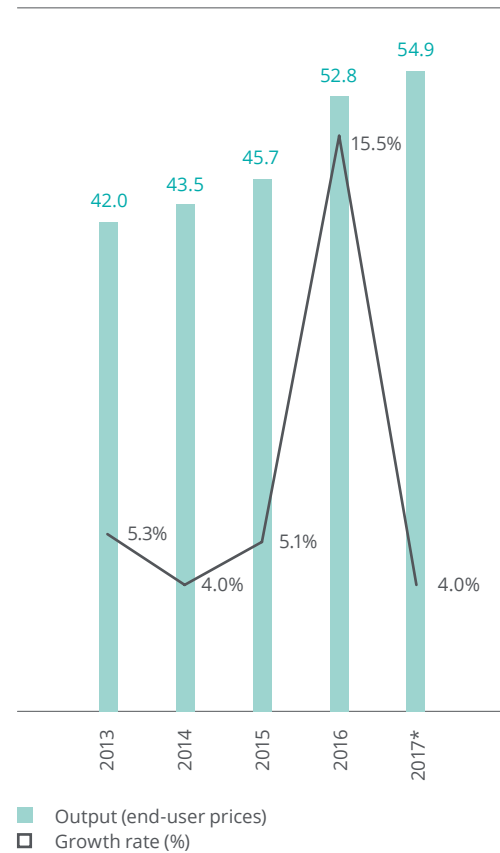


# Pharmaceutical output in Russia

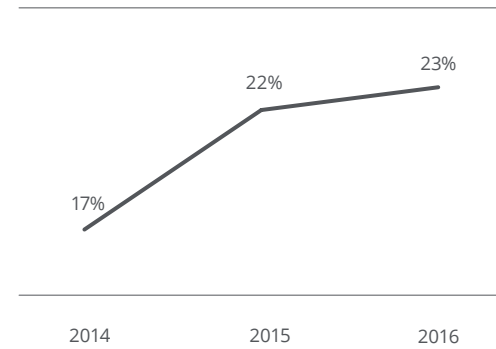
**Output of medicines in Russia (RUB billion)**



**Output of medical products in Russia (RUB billion)**



**Localized medicines as a percentage of the total output of medicines in Russia**



Source: Russian Ministry of Industry and Trade

**Expert view**

“Maintaining the existing growth rates on the Russian pharmaceutical market requires additional measures from the government.”

**Nikolay Bepalov,**  
Development Director, RNC Pharma  
in an interview to ITAR-Tass

**Trend**

The crisis that emerged by the end of 2014 has had a positive impact on the evolution of the pharmaceutical market. A weaker ruble and government measures helped Russian companies strengthen their positions while promoting import substitution and giving a localization impulse to foreign companies.

On the negative side, the crisis has also driven up prices for end consumers amid the deteriorating purchasing power of households.

**Forecast for 2017 by the Russian Ministry of Industry and Trade**

- The output of medicines will grow by 20 percent in unit terms and by 8 percent in ruble terms.
- The output of medical products will grow by 17.2 percent in unit terms and by 4 percent in ruble terms.

Source: Russian Ministry of Industry and Trade

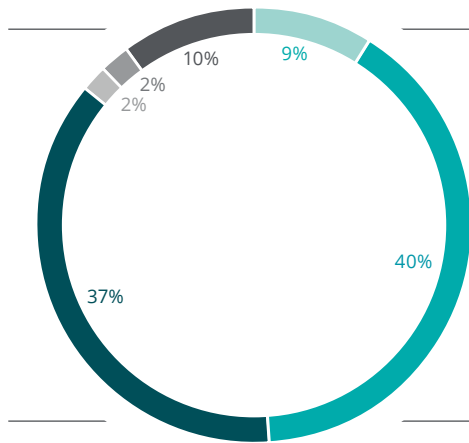
\*2017 forecast

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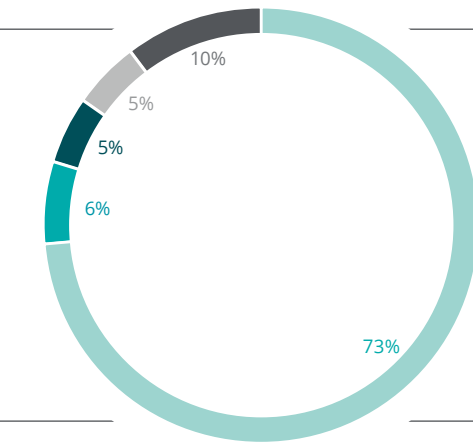
# Russian pharmaceutical market on the global map in 2016

Structure of exports



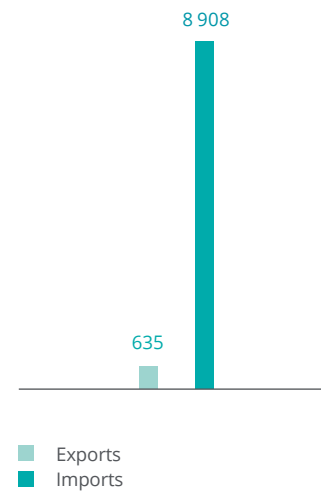
- EU
- EAEU
- CIS (except for EAEU)
- Georgia
- South Korea
- Others

Structure of imports



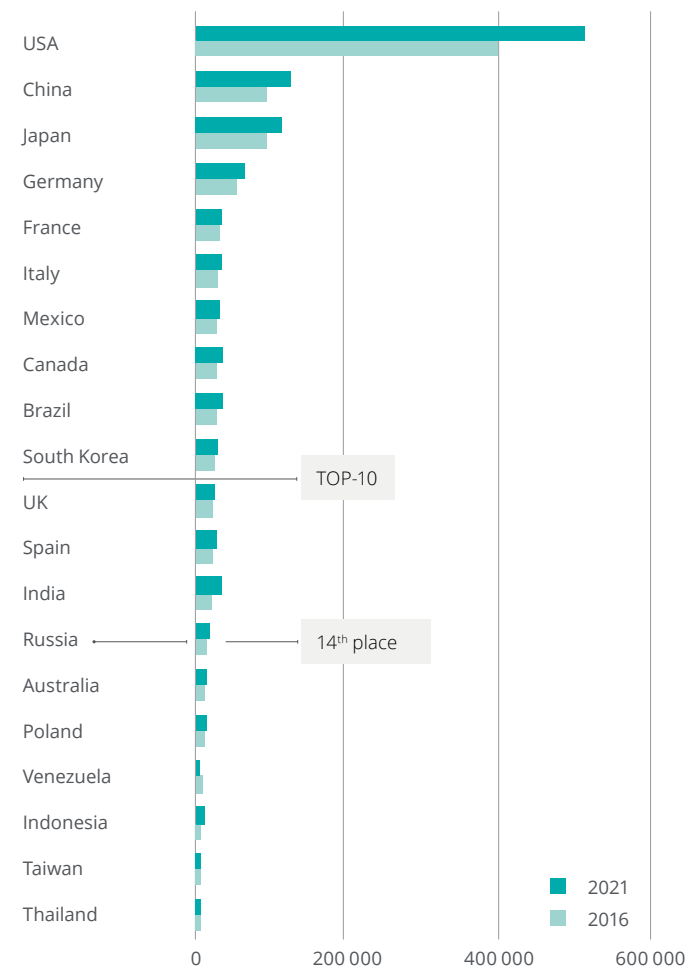
- EU
- USA
- Switzerland
- India
- Others

Russian exports and imports(USD million)



Source: Russian Federal Customs Service

Rx / OTC outputs (USD million)



Source: EIU

Source: Russian Federal Customs Service

- With pharmaceutical imports 14 times greater than exports, Russia is a net importer of medicines .
- Almost 80 percent of imports come from Europe, primarily from Germany and France.
- The post-Soviet countries remain the major export markets for Russian medicines, accounting for 86 percent of Russian exports.
- The EIU estimates that the global pharmaceutical market will grow by 26.3 percent in USD by 2021.
- Russia is outside the top 10 countries leading in terms of size. However, the EIU predicts a growth in sales by 31.4 percent for Russia over the next five years so that the country will keep its 14<sup>th</sup> place.



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# Overall situation on the Russian pharmaceutical market



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# Russian pharmaceutical industry: current situation



■ Positive  
■ Rather positive  
■ Rather negative

\* Beneficiary owners are Russian residents  
\*\* or the Russian subsidiary of a foreign company  
\*\*\* Positive views minus negative views

## Trend

- Spring 2017 saw a significant improvement in the sentiment on the Russian pharmaceutical market: the net sentiment\*\*\* is positive, up by 2.5 times from 2016.
- At the same time, almost one fourth of the respondents surveyed (24 percent) have a negative view of the situation, which is indicative of the continuing negative impact from the factors constraining the growth in the industry.

## Highlights

- Generic manufacturers (+14 pp) and Russian companies (+10 pp) have a more optimistic view of the situation on the market, which is a result of the positive developments for these companies
- At the same time, original drug manufacturers and pharmacies have a less upbeat view, which is below the average by 8-9 pp

- The year 2017 is also characterized by positive sentiment among foreign companies, including companies without localization in Russia. In 2016 this group generally maintained a negative view. However, this trend reversed by early 2017, with the number of positive responses growing from 46 percent to 73 percent

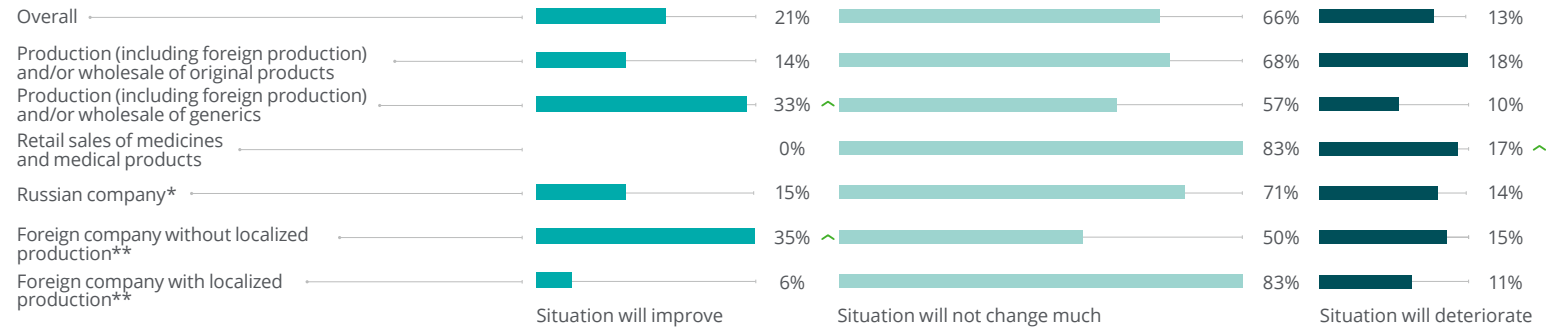
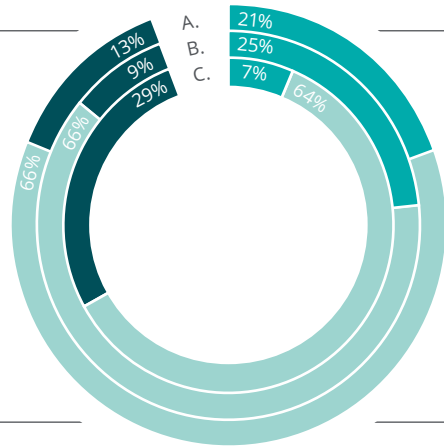
## View of a pharmaceutical manufacturer's representative

“The situation in the industry has significantly improved for foreign companies; we are past the crisis peak, with the economy demonstrating a nascent recovery and the appreciating ruble contributing to their [foreign companies] advantage.”

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# Russian pharmaceutical market: outlook for 2017



■ Situation to improve  
 ■ Situation not to change much  
 ■ Situation to deteriorate

A. Overall  
 B. Optimistic about the current situation  
 C. Pessimistic about the current situation

\* Beneficiary owners are Russian residents  
 \*\* or the Russian subsidiary of a foreign company

## Trend

According to the consensus forecast for 2017 by industry representatives, the situation will continue without change. Two thirds of the respondents (66 percent) do not expect any significant change. However, the respondents expressing optimistic views dominate among those who predict changes, with 60 percent expecting changes for the better in the industry.

The respondents with a positive view of the situation in the industry also generally maintain a positive view of the industry outlook; 73 percent of those expecting significant changes predict that the situation will improve.

It is quite the opposite with the respondents who have pessimistic views: a majority of them (64 percent) do not expect any improvements while another 29 percent expect a further deterioration in the market.

## Highlights

Generic manufacturers more often responded with “situation to improve” in 2017 (+12 pp).

Retail businesses were less optimistic, with 17 percent expecting the situation to deteriorate. No one in this group responded with “situation to improve”.

The last year saw a fundamental shift in how non-localized foreign companies view their

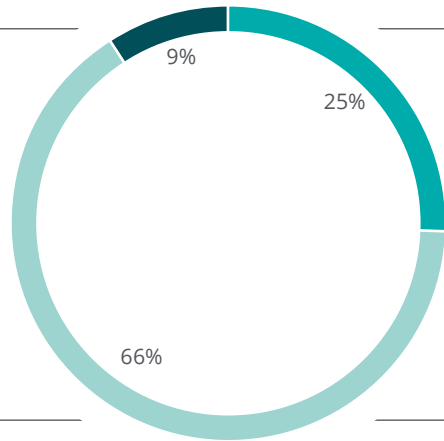
future prospects. In 2016 this group generally expressed negative views. However, this year more than one third of them (35 percent) expect the situation to improve. This may be due to the fact that after facing strong difficulties in 2015–2016\*\*\*, this group has a more optimistic view amid the stabilizing situation.

\*\*\* Adverse market situation, projectionist measures by the Russian government, weaker financial performance

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# Russian pharmaceutical companies: current situation



■ Positive  
■ Rather positive  
■ Rather negative

\* Beneficiary owners are Russian residents  
\*\* or the Russian subsidiary of a foreign company  
\*\*\* Positive views minus negative views

## Trend

With 91 percent of the respondents having a positive view of how their companies perform, the overall situation in the Russian pharmaceutical sector is clearly perceived as positive.

The overall optimism\*\*\* increased by 14 pp during the last year.

## Highlights

- Pharmacies more often tend to express a negative view, with one third (33 percent) responding with “rather negative”.
- At the same time, generic manufacturers are more optimistic (+9 pp).

## View of a pharmaceutical manufacturer’s representative

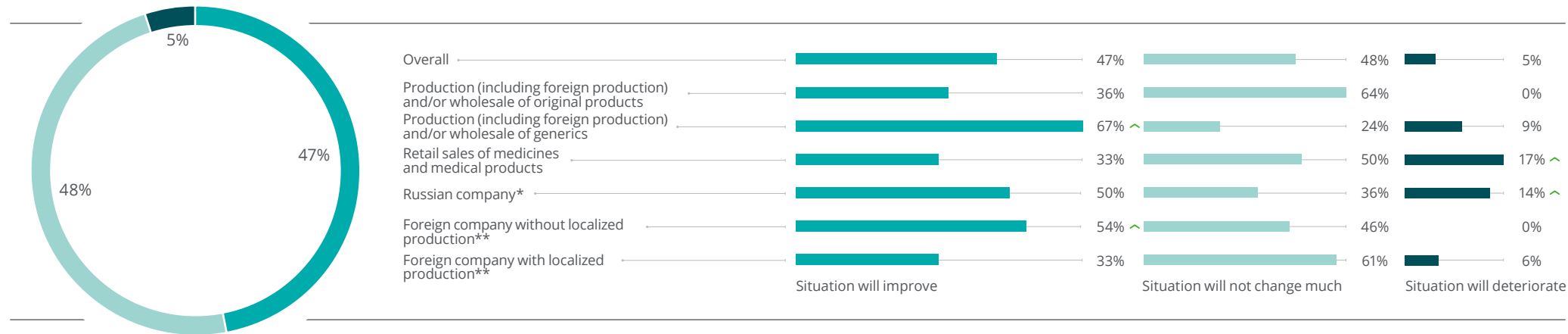
“The continuing consolidation on the pharmacy market is fueling fierce competition when dumping prices offered by large pharmacy chains, discounters and ‘killer’ pharmacies result in falling profitability.”

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# Russian pharmaceutical companies: outlook for 2017



■ Situation to improve  
 ■ Situation not to change much  
 ■ Situation to deteriorate

\* Beneficiary owners are Russian residents  
 \*\* or the Russian subsidiary of a foreign company

## Trend

The respondents have a divided view on the outlook for pharmaceutical companies, with 47 percent expecting improvement and 48 percent specifying that the situation will remain the same.

The prevailing positive views indicate that companies enjoy a favorable situation, but with some uncertainty still involved.

## Highlights

- Generic manufacturers are the most optimistic when it comes to the outlook for their companies, with 67 percent expecting the situation to improve.
- Retailers tend to be more pessimistic about the future, with 17 percent predicting the situation to deteriorate, which is three times higher than the average.

- Most Russian companies (68 percent) do not expect any deterioration. At the same time, another 14 percent point to potential deterioration.
- Unlike localized companies, non-localized foreign companies are much more optimistic about their future (+21 pp). As mentioned previously, such companies tend to respond positively even if it comes to simple stabilization.

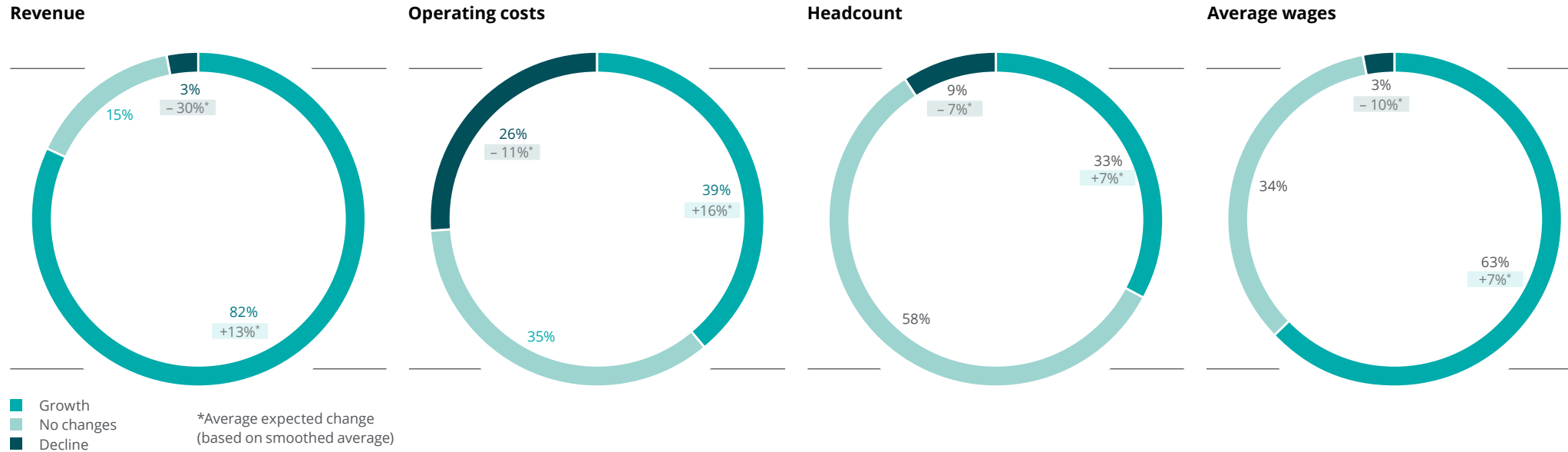
## View of a representative from a pharmacy chain

“Bureaucracy, lack of qualified specialists and insufficient financing - all deter development of Russian pharmaceutical companies”

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# Expectations for the key performance indicators on the Russian pharmaceutical market



- Positive expectations for the outlook of pharmaceutical companies and the industry are further reflected in the expectations for changes in the key performance indicators: Most companies (82 percent) expect to see their revenue grow by 13 percent in rubles in 2017.

- In practice, a growth in revenue is generally accompanied by a growth in operating costs. Our survey has found that 39 percent expect operating costs to grow by an average of 16 percent.
- At the same time, 26 percent are planning to reduce operating costs by an average of 11 percent while another 35 percent will keep their operating costs the same as in 2016.

- Due to their stabilized position, most companies (91 percent) do not need to reduce staff numbers.
- Two thirds of the companies (63 percent) are planning to increase the average pay level by 7 percent, which is almost twice as high as the inflation forecast by the Central Bank of Russia (4 percent).

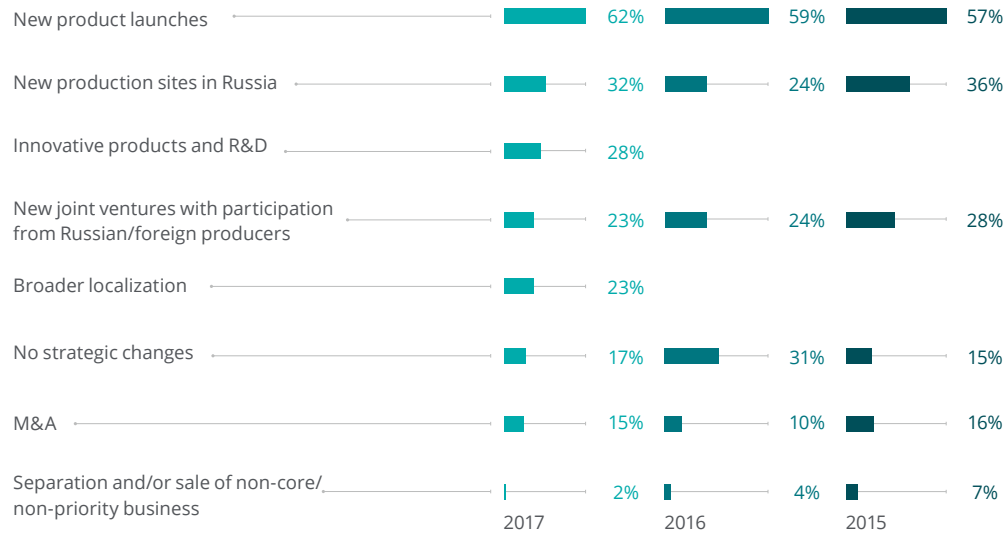
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# Pharmaceutical business development strategies for Russia



## Trend

A focus on product launches remains the top development strategy for pharmaceutical companies in Russia.

In 2017 companies are demonstrating more interest in strategies such as R&D (28 percent) and broader localization (23 percent), which indicates that the Russian pharmaceutical market is picking up.

## Highlights:

- **Launches of new products (62 percent)**  
This strategy is of more interest to generic manufacturers (88 percent) and non-localized companies (71 percent).
- **New production sites in Russia (32 percent)**  
This strategy is often chosen by companies that already have production sites in Russia (Russian companies: 56 percent; localized foreign companies: 50 percent). This generally includes large companies employing more than 1,000 people (70 percent).
- **R&D and innovative products (28 percent)**  
In Russia generic manufacturers more often engage in developing new generic products (35 percent), compared to original drug manufacturers (24 percent).

Almost half of the companies that expect improvements in their market situation (48 percent) view this strategy as the way to go.

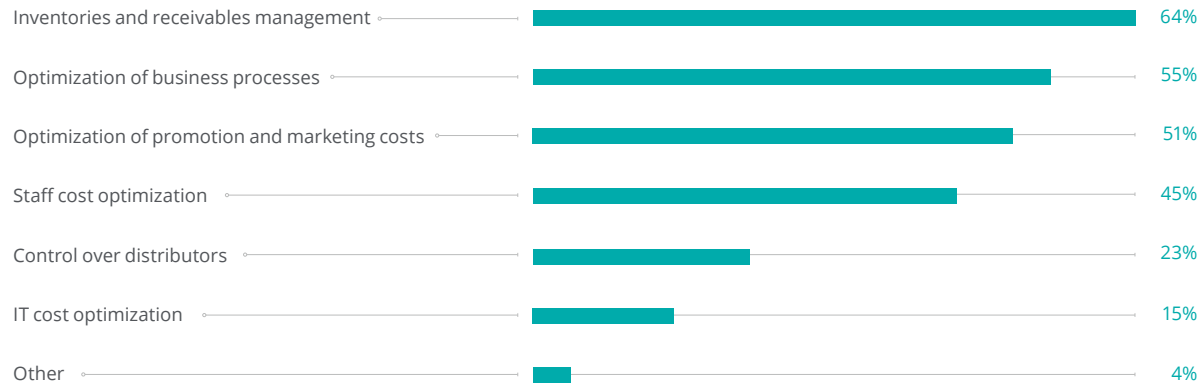
- **New joint ventures (23 percent)**  
Unlike Russian companies (11 percent), foreign manufacturers more often prefer setting up joint ventures (localized companies: 29 percent, non-localized companies: 25 percent).
- **Deeper localization (23 percent)**  
Almost every second foreign company (43 percent) with production facilities in Russia has plans for deeper localization. This strategy is also more popular with original drug manufacturers (28 percent).
- **No strategic changes in the pipeline (17 percent)**  
Over the last year, the group of companies without plans for strategic changes decreased from 31 percent to 17 percent. Companies with a negative view of their position more often avoid plans for changes (50 percent).
- **M&A plans (15 percent)**  
Russian companies (22 percent) more often tend to consider M&A deals as a way for growth.



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# Cost optimization approaches



## Trend

Businesses need full and correct information regarding the flow of medicines on the market to ensure efficient implementation of the cost optimization strategy. Unfortunately, this information is still difficult to access.

## Top 4 cost optimization strategies:

- Inventories and receivables management (64 percent)**

Companies with an annual revenue from RUB 1 billion to RUB 10 billion more often tend to maintain focus on working capital (81 percent).

- Business process optimization (55 percent)**

This cost optimization strategy is more often employed by large companies with an annual turnover above RUB 30 billion (71 percent), as well as by companies with hospital procurements as their major source of revenue (71 percent).

- Optimization of promotion and advertising costs (51 percent)**

Generic manufacturers more often tend to focus on the optimization of marketing costs (65 percent).

- Optimization of staff costs (45 percent)**

Most localized foreign companies (60 percent) have plans to optimize staff costs.



## Expert view

“The commercial segment is still facing a wave of growing receivables. As the retail segment consolidates into mid-size and large-size chains, pharmacies have to divert funds from their working capital amid the fight for a market share.”

**Oleg Berezin**  
Partner,  
Deloitte CIS



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# Track & trace system as a way to approach business process optimization



In February 2017 the government started a pilot project involving a number of companies across the supply chain. Which is aimed at testing a track & trace system. According to the existing schedule, the across-the-industry deployment of the system is expected to be completed by 1 January 2019.

While this system is designed to protect consumers against adulterated drugs and ensure a quick removal of counterfeit and low-quality products from the market, it will also provide authorities with control over the flow of products on the market. For instance, participation in design and implementation of track&trace system has already been reflected in the development program for the Russian Federal Customs Service for a period until 2020. With the Russian Federal Tax Service as

an operator of the track & trace system, data inputs are also likely to be used for the purpose of tax control. Therefore, the deployment of the system requires the involvement of tax, finance, customs and legal experts.

The deployment will inevitably lead to additional software implementation costs and expenses for the purchase of labelling and scanning equipment. However, the system also has huge potential for pharmaceutical manufacturers and distributors as it can provide them with access to valid data, enabling a near real-time analysis of the flow of medicines on the market. Businesses can further benefit from such data and analysis as they implement their strategies aimed at a higher turnover of inventories and more efficient control over receivables, which are the two key priority areas for market participants

looking to optimize their costs. In addition, the track & trace system will generate data arrays that can be analyzed to optimize promotional and advertizing campaigns. This may result in a significant change in the legal and financial interactions between producers/distributors and pharmacies, as well as in a major disruption in the market. Manufacturers and importers that act quicker to gain access to data on sales of their products in the track & trace system (e.g. by purchasing data from distributors and pharmacies) will be able to gain a significant edge, strengthening their position or winning over some share from the market leaders.

**Oleg Berezin**  
Partner,  
Head of Life Sciences & Healthcare  
Industry Services in the CIS

## View of a representative from a large pharmacy chain

“The track & trace system above all means additional OPEX and CAPEX for a business, which will inevitably result in higher sale prices. However, it will curb illegal drugs to a significant extent, which is an important factor as far as health security of Russian citizens is concerned. This is a complicated process, but a step into the future never comes without challenges.”

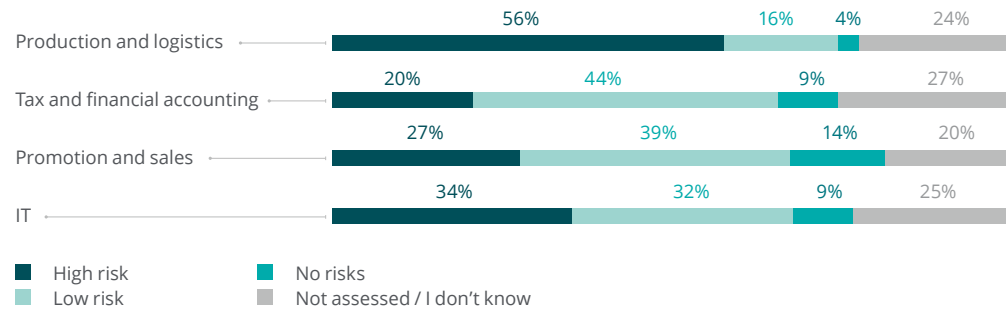
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# Preparations for implementing the track & trace system

The survey has provided us with insight into how our respondents assess the implementation risks facing their business units and what preparations they are taking to prepare for the changes.



**?** In terms of the introduction of the track & trace system, do you see any risks for the business functions within your company?



### Trend

Experts cite production and supply chain processes as most vulnerable to risk, with 56 percent mentioning the high risk involved in the implementation of the track & trace system. Non-localized companies demonstrate the highest level of concern, with 63 percent already seeing a strong risk coming from the potential negative impact on production units and logistic functions. Another concern is about the IT function, which is responsible for ensuring

an uninterrupted data exchange. In regard to commercial and accounting functions, more than half of the respondents (53 percent) do not see any significant risks, which may be due to a lack of deeper insights in related areas.

### Highlights

At the same time, about one fourth of the respondents replied with “don’t know” when asked about risk exposure for their business functions. This is because the pilot track & trace system only started as we conducted the survey, with the market waiting for the first results and more definitive steps from the government.

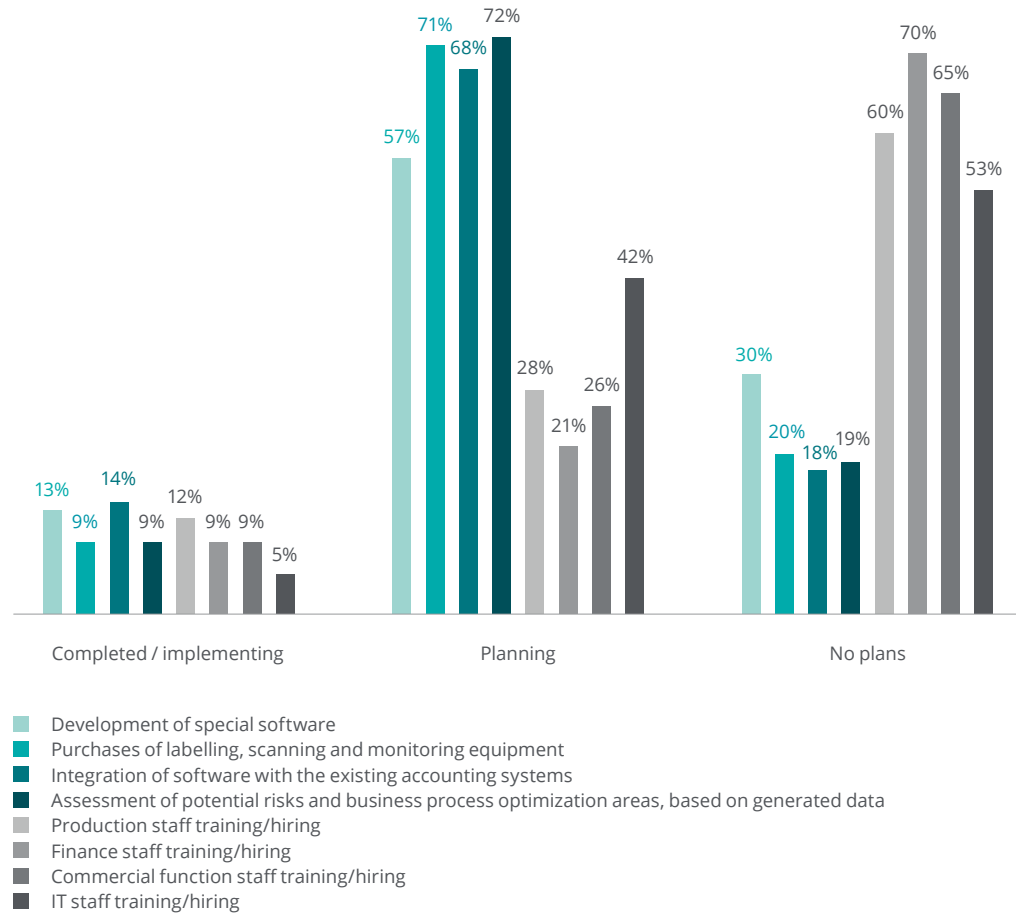
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? Please specify whether your company is implementing or planning to implement these initiatives as part of the preparations for implementing the track & trace system?



#### Trend

In terms of the preparations, the focus is primarily on equipment purchases (80 percent) as well as on software development and integration (70 percent and 82 percent, respectively). However, most of the respondents do not believe that hiring new talent and providing focused training is necessary.

Furthermore, experts have started assessing potential benefits and risks of using generated data.

#### Highlights

Waiting for results of the pilot project explains the relatively low completion rates with only 15 percent of the companies going about the initiatives.

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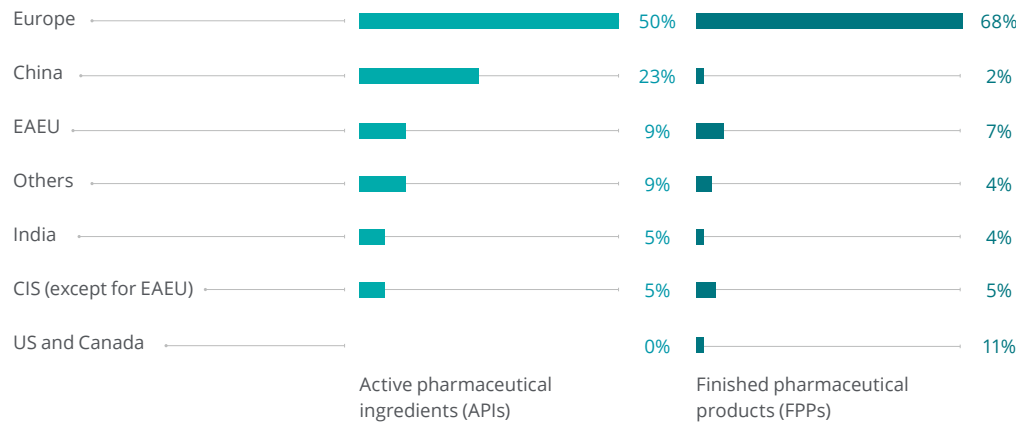
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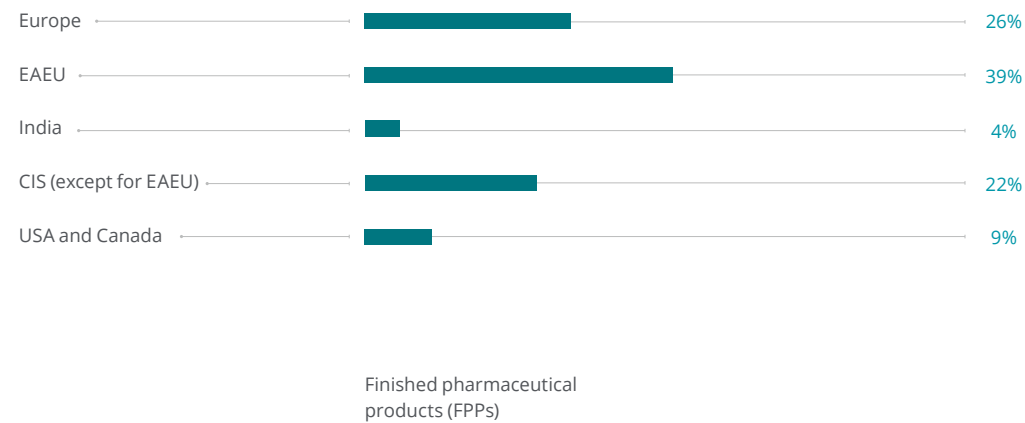


# The foreign trade structure on the Russian pharmaceutical market

Share of importers\* (%)



Share of exporters\* (%)



**Trend:**

Of the respondents surveyed, 78 percent indicated that their companies import Finished pharmaceutical products (FPPs) and 31 percent said that their companies import Active pharmaceutical ingredients (APIs).

- Europe accounts for a major portion of the imports of APIs and FPPs for Russian pharmaceutical companies (50 percent and 68 percent, respectively).
- Almost one fourth of the importers (23 percent) purchase APIs from China. However, as regards FPP imports into Russia, Chinese producers account for a tiny portion of these imports (2 percent).

**Highlights**

Generic manufacturers (56 percent) and localized foreign companies (50 percent) are the most frequent importers of APIs.

Original drug manufacturers (51 percent) and non-localized foreign companies (53 percent) are the most frequent importers of FPPs.

**Trend**

Almost one third of the respondents (29 percent) are exporters of FPPs

- As mentioned earlier, the post-Soviet countries represent a major export market for Russian pharmaceutical products, with 39 percent of exporters shipping their products to the countries in the Eurasian Economic Union (EAEU) and 22 percent to other CIS countries.
- More than one fourth of the exporters (26 percent) responded that they ship products to European countries.

**Highlights**

Generic manufacturers (59 percent) are the most frequent exporters of FPPs.

As exports of APIs were only indicated by 7 percent of the respondents, we do not have sufficient data to analyze the geography for the exports of substances.

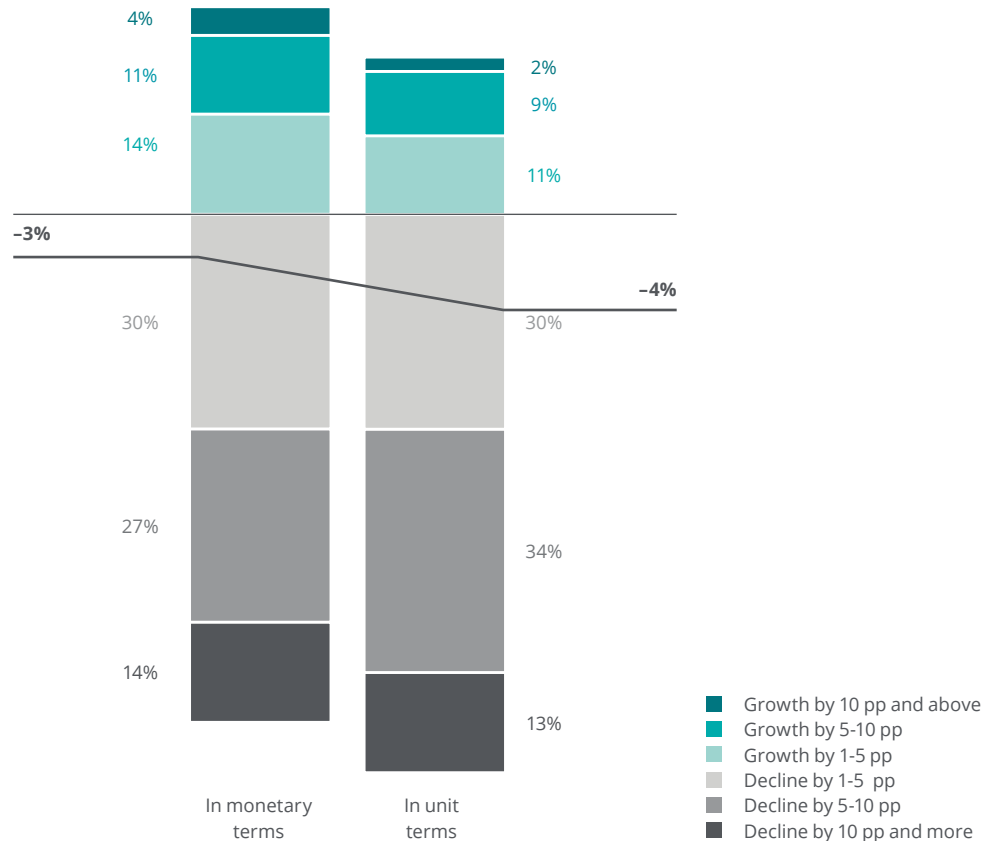
\*Please note that this import/export structure is relevant for the sample of our survey. Please see "Our Respondents" for more details.

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# Economic expectations: pharmaceutical imports in Russia

? How will the share of pharmaceutical imports change on the Russian market over the next two years?



### Trend

Based on the consensus forecast by representatives from pharmaceutical companies, pharmaceutical imports will decline by 4 percent in unit terms and by 3 percent in monetary terms.

Of the respondents surveyed, 64 percent expect that pharmaceutical imports will decrease within a range of up to 10 pp in unit terms and 57 percent expect a similar decrease in monetary terms while only 13 to 14 percent expect a more significant decrease.

At the same time, almost one third of the respondents surveyed (29 percent) expect an increase in pharmaceutical imports in monetary terms. A slightly lower number of respondents (22 percent) expect that pharmaceutical imports will see a growth in unit terms.

### Highlights

The representatives from foreign companies expect a sharper decline in pharmaceutical imports in unit terms, with 42 percent predicting a decline from 5 pp to 10 pp, while 42 percent of the representatives from Russian companies predict a decline of up to 5 pp.

Companies operating in the hospital procurement or hospital sales segment expect a stronger decline from 5 pp to 10 pp in unit terms (63 percent) while companies from the commercial segment predict a decrease of up to 5 pp (33 percent). This is expected since Russian medicines dominate the hospital procurement or hospital sales segment with a share of 73 percent in unit terms while for the commercial segment this share is only 57 percent, according to data available by the end of 2016.

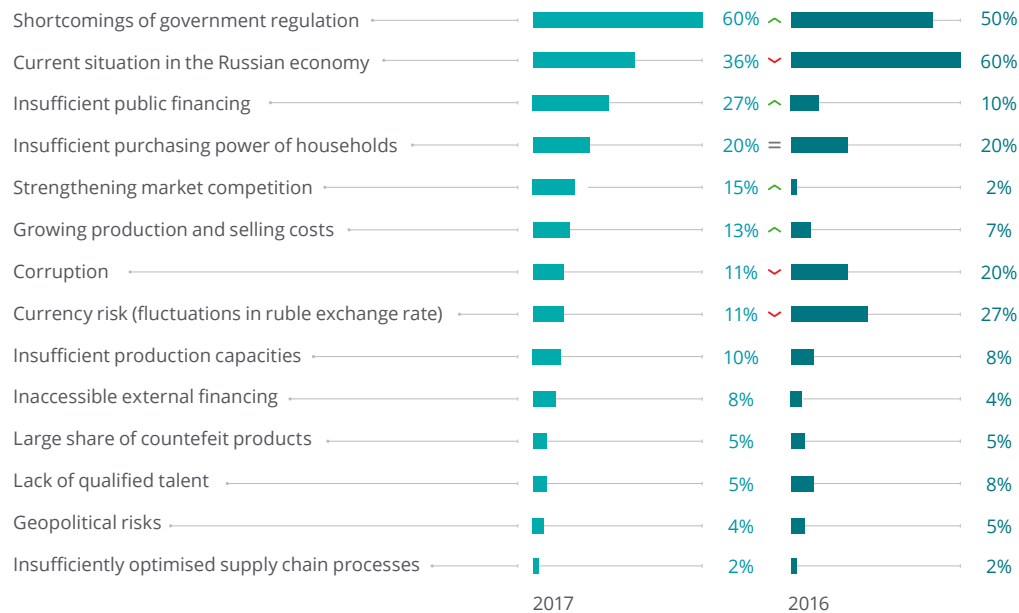


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# Top-14 issues facing pharmaceutical companies in Russia

**?** Please select and prioritize the top three issues pharmaceutical and healthcare companies face in Russia today.



## Trend

Our survey has shown that the pharmaceutical market's concern has shifted from macroeconomics to government efficiency in 2017.

In 2017 experts are less concerned over the situation in the Russian economy, with an annual decrease in concern down by 24 pp. At the same time, the shortcomings of government regulation have been voted as the top issue (60 percent).

Another significant concern for pharmaceutical respondents is insufficient public financing, with 27 percent voting for it in 2017, compared to only 10 percent in 2016.

Forex risks have seen a significant decrease in importance (-17 pp).

In 2017 strengthening competition on the market poses a concern for more companies (+13 pp), reflecting the fact that the market is picking up after the economic events of 2014-2015.

## Highlights

- **Shortcomings of government regulation (60 percent)**  
This is above all the top issue for localized and non-localized foreign companies (69 percent and 64 percent, respectively) while Russian companies pay significantly less attention to it (40 percent).
- **Situation in the Russian economy (36 percent)**  
The representatives from large companies demonstrate a stronger concern over the situation in the economy: 45 percent of the companies with an annual turnover of RUB 10 billion to RUB 30 billion and 49 percent of the companies with an annual turnover above RUB 30 billion.

- **Insufficient public financing (27 percent)**  
Understandably, this issue is of utmost concern for businesses focusing on hospital sales (45 percent), as well as on sales that are part of the State Reimbursement Program (ONLS/DLO) (77 percent)
- **Insufficient purchasing power of households (20 percent)**  
This issue comes fourth in importance for the second year in a row. As a constraint to growth, it has the strongest impact on non-localized foreign companies operating in Russia (32 percent).
- **Strengthening market competition (15 percent)**  
In 2017 Russian companies more frequently cite growing competition (23 percent).

## Expert view

“As consolidated on public procurement spending continues to decline in real terms, the government places particular emphasis on more efficient spending, mainly by focusing on more active steps in the area of anti-monopoly policy, price regulation and import substitution. At the same time, the discussion of cost optimization through more efficient medical treatment, including risk-sharing models, has only started.”

**Oleg Berezin**  
Partner, Deloitte CIS



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# Efficiency of government regulation in the industry

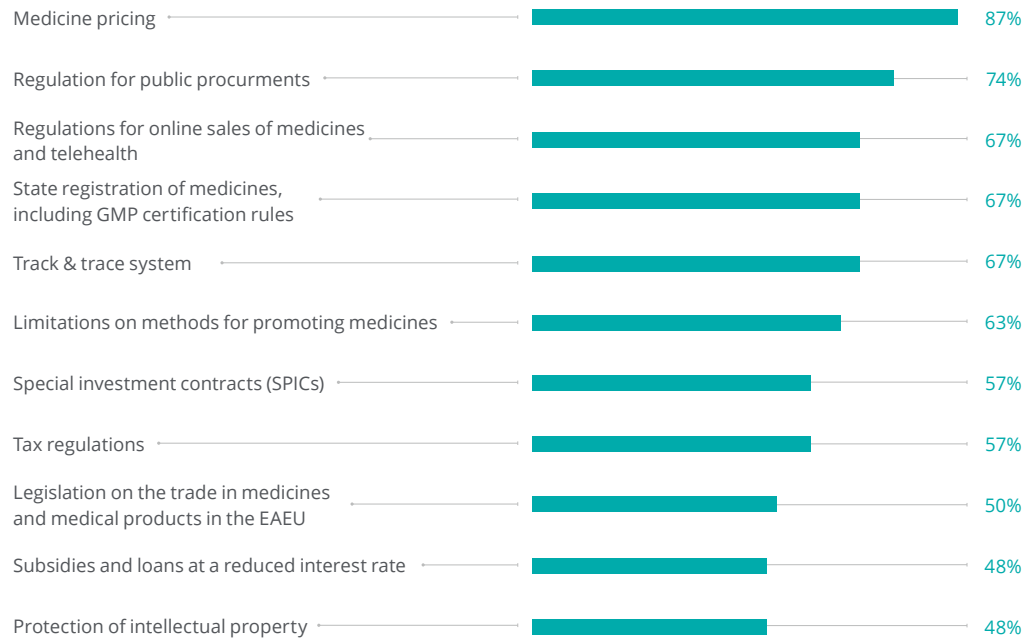


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# Priority areas requiring better government regulation

As mentioned previously, pharmaceutical experts perceive government regulation to be the top issue facing the industry. Based on the survey, we have identified top areas for improvement.



## Trend

The respondents surveyed note, above all, the need for more efficient government medicine pricing policies (87 percent) and better public procurement regulations (74 percent). As regards areas requiring more efficient government regulation, these remain the top concern for a third year in a row.

These concerns are closely followed by the following issues (67 percent): regulations of online sales, state registration and certification and the implementation of the track & trace system.

## Highlights

**Medicine pricing, including the procedure for updating the Essential Drug List and the related price calculation methodology (87 percent)**

Almost all the respondents indicated the need for better price regulations. The respondents from large companies are less concerned over this issue: 71 percent of the companies with a revenue above RUB 30 billion and 70 percent of the companies with a headcount above 1,000.

**Public procurement regulations (e.g. practices for applying preferences or restrictions as regards public procurements or the procedure for purchases based on the trade name list) (74 percent)**

The recent years have been characterized by a pronounced protectionist policy in public procurements, with a focus on import

substitution. This is the reason why foreign producers more often cite the need for changes in this area. In 2016 localized foreign companies expressed a far stronger concern over this issue (77 percent), compared to non-localized companies (42 percent). However, the year 2017 has seen the priority of this issue becoming equally relevant for all foreign companies (80 percent).

**Regulations over online sales of medicines and healthcare services (online pharmacies and telehealth providers) (67 percent)**

Companies focusing on the commercial segment are more interested in having rules that would regulate online sales of medicines and telehealth (76 percent). The State Duma approved the related legislative act at first reading on 15 June 2017.

**State registration of medicines, including rules regulating the GMP certification of production sites (67 percent)**

Original drug manufacturers (81 percent) and foreign companies (73 percent) more often cite the need for better registration and certification regulations.

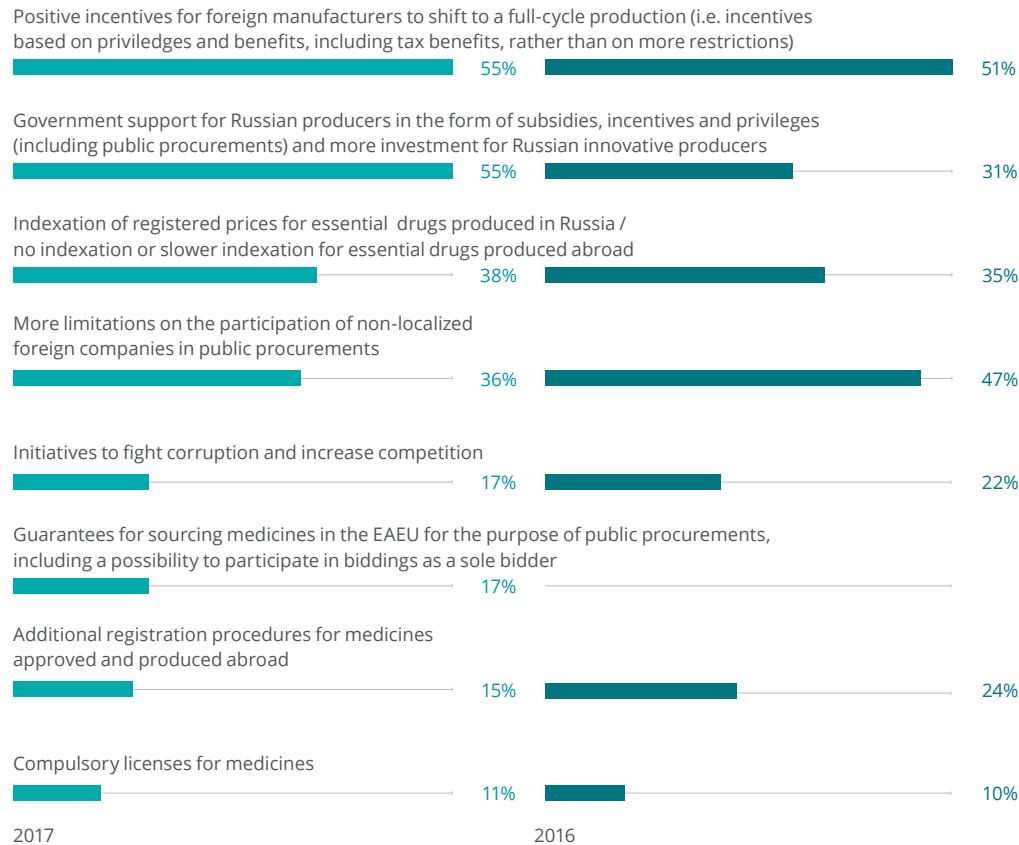
**Track & trace framework (67 percent)**

The track & trace system is a priority area for Russian companies (85 percent) and localized foreign companies (73 percent).

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# Government initiatives aimed at reducing the share of pharmaceutical imports



- As in 2016 the respondents see incentives and privileges, rather than restrictions and limitations, as the key to promoting localization to reduce pharmaceutical imports. They believe that subsidies and privileges are also important for Russian producers (55 percent).
- There has been a significant decrease in the number of respondents who would like to see stricter requirements for foreign producers participating in public procurements (-11 pp). This may be due to the fact that public procurements already impose relatively strict, protectionist requirements. Specifically, this is required by Russian Government Regulation No. 1289 "On restrictions and participation requirements for foreign medicines included in the Essential Drug List for the purpose of procurements for federal and municipal

needs" of 30 November 2015. As of 1 January 2017 for the purposes of applying the aforementioned Resolution all drugs undergoing solely primary and secondary packaging in member states of EAEU are not considered local products. The origin of the products is also important, due an obligatory discount of 15% applied to the price of foreign-origin medicines in case a relevant bidder wins a government procurement tender.

- Pricing regulations for products from the Essential Drug List continue as one of the top issues. This is clearly a non-market mechanism that affects the profitability of medicines included in the Essential Drug List, which could ultimately result in scaled-down production of certain medicines, including products priced below RUB 50.

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# Our respondents



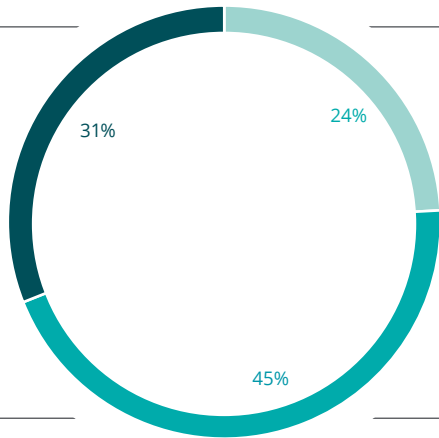
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# Our respondents

Company type

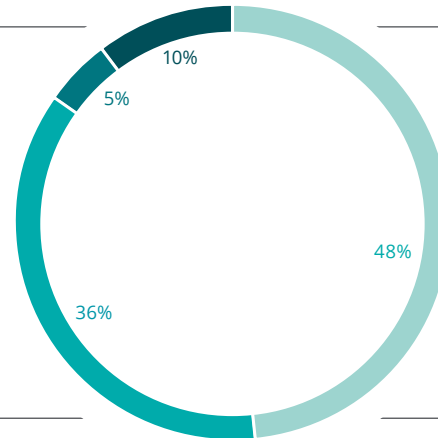


- Russian company whose beneficiary owners are Russian residents
- Foreign company or Russian subsidiary of a non-localized foreign company
- Foreign company or Russian subsidiary of a localized foreign company

As in 2016 almost half of the respondents surveyed are representatives of non-localized foreign companies (45 percent).

The other respondents come from Russian companies (24 percent) and localized foreign companies (31 percent).

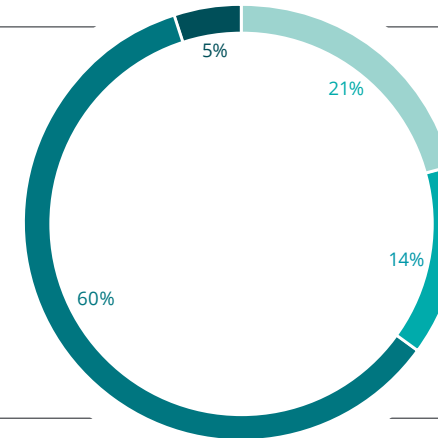
Company's core operations



- Production (including foreign production) and/or wholesale of original medicines as a predominant activity
- Production (including foreign production) and/or wholesale of generics as a predominant activity
- Production (including foreign production) and/or wholesale of medical devices (equipment) as a predominant activity
- Retail sales of medicines and medical products

Most of the respondents represent pharmaceutical companies, with 48 percent coming from original drug manufacturers and 36 percent from generic manufacturers.

Respondent's job function



- Management
- Sales
- Finance
- Other

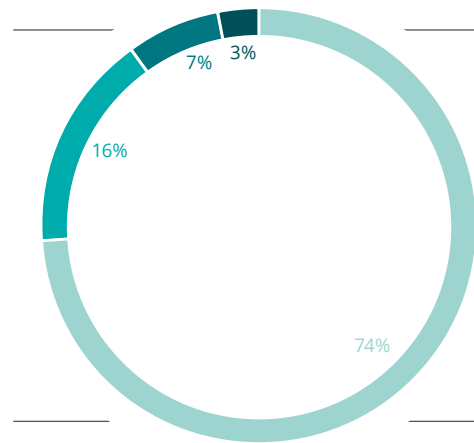
The majority of respondents are finance professionals (60 percent), executives (21 percent) and sales function representatives (14 percent).

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# Our respondents

Key sales channel

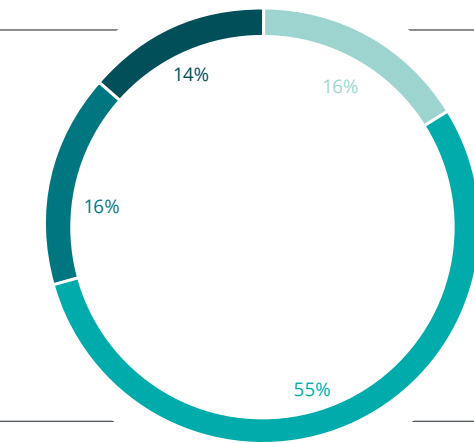


- Commercial segment (pharmacies)
- Hospital procurements
- Regional/municipal procurements under the State Reimbursement Programme (ONLS/DLO)
- "Seven rare diseases" and other federal programmes

The commercial segment is a major sales channel for most of the respondents (74 percent).

Hospital purchases represent a major source of revenue for 16 percent of the companies surveyed.

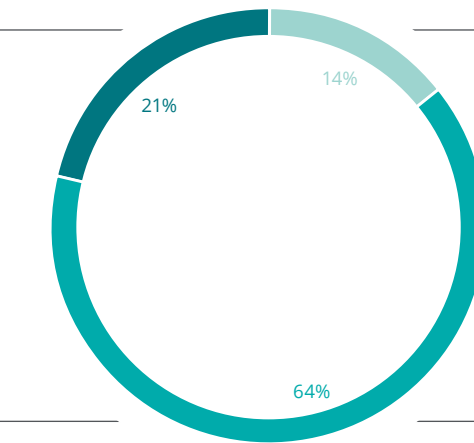
Annual revenue



- Below RUB 1 billion
- From RUB 1 billion to RUB 10 billion
- From RUB 10 billion to RUB 30 billion
- Over RUB 30 billion

Our survey covers both large and small companies in terms of revenue. Companies with a revenue from RUB 1 billion to RUB 10 billion represent a majority of the survey (50 percent).

Headcount



- Below 100 employees
- From 100 to 1,000 employees
- Over 1,000 employees

A majority of the respondents are from mid-size companies (64 percent). Other respondents represent companies with a headcount above 1,000 employees (21 percent) and small companies with a headcount below 100 employees (14 percent).

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